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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/099,858

03/14/2002

Bonnie M. Davis

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4479

140 7590 04/27/2011

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NEW YORK, NY 10018-3738

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1627

NOTIFICATION DATE

DELIVERY MODE

04/27/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/099,858	<b>Applicant(s)</b> DAVIS, BONNIE M.	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-36,38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 5-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 38 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicants point out that the 35 USC 102(b) rejection is improper because the publication date of the reference was less than one year before the effective filing date of the present application. It is recognized that the 35 USC 102(b) rejection was mistakenly used in the rejection; the rejection should have been a 102(a) and is being maintained herein as a 102(a) reference.

Applicants argue that Coe does not anticipate the present claims because essential steps in determining the LDL-cholesterol value for patients and administering the specified compounds to patients whose LDL was determined to be below 109 mg/dl. It is argued that Coe teaches to combine a cholinesterase inhibitor with an NRPA to treat cognitive dysfunction and does not suggest to use galanthamine as the only active in treating the particular class of patients specified in the present claims.

In response to the above arguments, it is noted that the present claims use “comprising” language, which is open-ended and does not exclude additional, unrecited elements or method steps. Therefore, the argument that galanthamine is not the only active in treating the particular class of patients specified in the present claims is not persuasive because the claim allows for the inclusion of other elements. Further, the claims limitation of treating cognitive dysfunction of “a patient associated with low LDL-cholesterol values in serum” was not afforded patentable weight as discussed in the rejection because the treatment of cognitive dysfunction will occur despite how the cognitive dysfunction began. Accordingly, please see the modified rejection below.

***Claim Rejections – 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-4, 38 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Coe et al. (US PgPub 2001/0036949).

Coe et al. teach pharmaceutical compositions for the enhancement of cognition or the treatment of disorders involving cognitive dysfunction in a mammal comprising administration of a composition that comprises an acetylcholinesterase inhibitor such as galanthamine (paragraphs 0010 and 0142). Cognitive dysfunctions include mild cognitive impairment, age-related cognitive decline, vascular dementia, Parkinson's disease, dementia, Huntington's disease, stroke, traumatic brain injury, AIDS associated dementia and schizophrenia (paragraph 0146). Coe et al. teach therapeutic doses of galanthamine in paragraph 0338.

It is noted that the treatment of cognitive dysfunction will occur regardless of the etiology of the dysfunction. Therefore, the claim limitation of treating cognitive dysfunction of "a patient associated with low LDL-cholesterol values in serum" is not afforded patentable weight as the treatment of cognitive dysfunction will occur despite how the cognitive dysfunction began.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1627

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627